IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF BRIAN N. SCHWARTZ, M.D.

Dr. Schwartz is an accomplished urologist who has performed over 600 surgical implantations of synthetic mid-urethral slings—hundreds of which involved Ethicon's TVT-O or TVT-Secur products. He is well qualified to offer his proposed testimony, which is supported not only by his substantial clinical experience but also by high-quality scientific evidence. He relied on systematic reviews, meta-analyses, randomized clinical trials, and other high-quality studies in forming his opinions on the safety and efficacy of these products and related matters. His opinions are based on "good grounds" and will assist the trier of fact to understand the evidence and determine facts in issue—namely, whether these products are defective and whether Plaintiffs can meet their burden of establishing general and specific causation. Accordingly, Ethicon requests that the Court deny Plaintiffs' motion to exclude Dr. Schwartz's testimony.

ARGUMENTS AND AUTHORITIES

I. Dr. Schwartz Has the Necessary Qualifications and Experience to Offer His Opinions on Mesh Properties.

Dr. Schwartz is well qualified to testify on the properties and characteristics of the mesh used in the TVT-O and TVT-Secur. He is a full-time practicing urologist and a member of the

American Urological Association. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 1. In his more than 20 years of practice, he has completed over 600 procedures involving the implantation of synthetic midurethral slings, several hundred of which involved the TVT-O or TVT-Secur. *Id*. at 1-2; Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 1-2. He has trained both urologists and gynecologists on the use of the TVT-O and TVT-Secur, as well as other synthetic mid-urethral slings. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 2. He has performed approximately 30 surgical revisions or excisions of mesh slings. Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 25:23-26:2. And in addition to his education and experience, he relied on dozens of peer-reviewed scientific articles in forming his opinions. *See generally* Exs. B & C to Pls.' Mot. (Dkt. 2089-2, 2089-3).

Plaintiffs assert that Dr. Schwartz is not qualified to offer opinions regarding "the material properties of polypropylene used in the TVT-O and the TVT-Secur" because he "does not have any experience in material science or designing a mesh product, has never analyzed, tested, or studied polypropylene mesh, and has never looked at mesh under a microscope . . . ." Pls.' Mem. (Dkt. 2090) at 4. Yet this Court has repeatedly allowed medical doctors with relevant clinical experience to offer opinions regarding the characteristics of polypropylene.

In *Huskey*, for example, the plaintiffs moved to exclude the degradation-related opinions of Dr. Harry Johnson, an obstetrician and gynecologist, on the grounds that he was "unqualified to opine about polypropylene because he is not a biomaterials expert." *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 733–34 (S.D.W. Va. 2014). The Court allowed the testimony, noting that "an expert 'need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion.'" *Id*. at 734 (quoting *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989)). The Court found that Dr. Johnson was qualified to offer his opinions on the

basis of his experience implementing "750 TVT or TVT-O devices," his treatment of patients with mesh-related complications, and his experience conducting clinical trials. *Id*.

The Court also determined that plaintiffs' expert urogynecologist, Dr. Bruce Rosenzweig, was qualified to offer opinions regarding mesh degradation, fraying, and particle loss based on his experience explanting mesh products, despite that Dr. Rosenzweig had not done any bench or lab research regarding polypropylene. *Id*. at 706-07. As the Court noted, "Simply because Dr. Rosenzweig has not personally performed pathology research on polypropylene explants does not necessarily render him unqualified under Rule 702 to offer opinions regarding the suitability of the TVT device for implantation. An expert may be qualified by 'knowledge, skill, experience, training, or education.'" *Id*. at 706 (quoting FED. R. EVID. 702); *see also id*. at 707 (finding Dr. Rosenzweig qualified to offer mesh-related opinions in part on the basis of his citation to dozens of studies and academic papers to support those opinions). Dr. Schwartz has similar types of experience as these experts and is therefore qualified to offer his opinions on the material properties of polypropylene.

Plaintiffs also make a generalized attack on Dr. Schwartz's qualifications to testify regarding "the design of pelvic mesh products," citing the Court's determination that three other experts were not qualified to testify regarding device design. Pls.' Mem. (Dkt. 2090) at 6-8. Plaintiffs' reliance on these rulings is misplaced:

- The Court determined that the plaintiffs' urology expert, Dr. Jerry Blaivas, in *Tyree v. Boston Scientific Corp*., 54 F. Supp. 3d 501, 561 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014), was not qualified to offer the opinion that "[a] permanent device, such as BSC Advantage and Pinnacle, should not have been designed to be placed in a surgically contaminated field." Plaintiffs here have not identified any similar opinions of Dr. Schwartz that they wish to challenge. *See generally* Pls.' Mem. (Dkt. 2090). The Court's ruling in *Tyree* is therefore inapposite.

- Plaintiffs cite the Court's ruling in *Huskey*, 29 F. Supp. 3d at 725, excluding testimony of Ethicon's toxicology expert, Dr. Michael Greenberg, relating to biocompatibility and mesh degradation. Pls.' Mem. (Dkt. 2090) at 7. Plaintiffs have not identified any biocompatibility opinions of Dr. Schwartz that they challenge. And Plaintiffs do not explain how the determination that a toxicologist is not qualified to testify regarding degradation is relevant to the determination of whether a urologist such as Dr. Schwartz may do so. Dr. Schwartz's experience is more analogous to that of Dr. Rosenzweig, who was deemed qualified to offer degradation opinions. *Huskey*, 29 F. Supp. 3d at 706-07.

- In *Wise v. C.R. Bard, Inc.,* No. 2:12-CV-01378, 2015 WL 570070, at *4 (S.D.W. Va. Feb. 11, 2015), Dr. Marshall Austin, a pathologist, was deemed qualified to testify regarding biocompatibility but was not permitted to offer his opinion that the defendant's products "d[id] not have inherent design defects," because opinions about the products' "overall design" exceeded his expertise. As mentioned above, Plaintiffs have not identified any biocompatibility opinions of Dr. Schwartz that they challenge. Nor have they explained how the determination that a pathologist is unqualified to offer design opinions informs whether a urologist is qualified to do so.

The clinical significance of the mesh-related issues on which Dr. Schwartz proposes to testify—including alleged mesh degradation, shrinkage, pore size, and density—is a central focus of this litigation. Dr. Schwartz's clinical experience will help the trier of fact evaluate the significance of other evidence and testimony (*e.g.*, that of a pathologist or a polymer scientist) in determining whether there is a defect in the product at issue and whether Plaintiffs have met their burden of establishing general and specific causation. Accordingly, the Court should find that Dr. Schwartz is qualified to offer the proposed testimony.

II. Dr. Schwartz's Opinions on the Properties and Characteristics of the Mesh Used in the TVT-O and TVT-Secur Are Reliable.

Dr. Schwartz's opinions are based not only on his deep clinical experience but also on the substantial body of medical literature studying the safety and efficacy of pelvic mesh products. This scientific literature includes, among other sources, systematic reviews and meta-analyses and randomized clinical trials. *See, e.g.*, Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at nn.20, 22-24 (citing systematic reviews and meta-analyses); *id.* at nn.8, 15, 18 and

accompanying text (discussing randomized clinical trials); *see also* Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 24:7-14. "A fundamental principle of evidence-based medicine . . . is that the strength of medical evidence supporting a therapy or strategy is hierarchical. When ordered from strongest to weakest, systematic review of randomized trials (meta-analysis) is at the top, followed by single randomized trials, systematic reviews of observational studies, single observational studies, physiological studies, and unsystematic clinical observations." FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 687, 723-24 (3d ed. 2011). Dr. Schwartz's opinions are based on the highest-level scientific evidence on the subject, as well as his more than 20 years of clinical experience with these products. His opinions are reliable, relevant, and admissible.

A. Dr. Schwartz's Opinions Regarding Laser-Cut and Mechanically Cut Mesh Are Reliable and Would Be Helpful to the Jury.

Dr. Schwartz believes that both laser-cut and mechanically cut TVT mesh is safe, effective, and state of the art. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 28. He has used TVT slings made of both types of mesh extensively in his practice and has "not found there to be a clinically significant difference in the way the mesh itself performs." *Id.* He has not observed the fraying, roping, or curling suggested by Plaintiffs' experts, nor is he "aware of published studies indicating the presence of such issues or any clinical significance." *Id.*

Plaintiffs claim that Dr. Schwartz's opinions on this subject are unreliable because he does not keep a log or registry of his patients who have been implanted with laser- versus mechanically cut mesh. Pls.' Mem. (Dkt. 2090) at 5. Plaintiffs do not explain, however, why such precise data would be required to support these opinions. That Dr. Schwartz does not keep a registry documenting that he has not observed any meaningful difference in the way the two types of mesh perform in the hundreds of procedures in which he has used them does not render

his opinions unhelpful or unscientific. Plaintiffs are free to establish on cross-examination that Dr. Schwartz does not keep such a registry, but they have not shown how his failure to do so makes his opinions inadmissible.

Plaintiffs also attack Dr. Schwartz's opinions on the grounds that he "states that literature supports mechanically-cut mesh, but acknowledges that medical literature does not differentiate between laser-cut and mechanically-cut mesh." *Id*. at 5. While Dr. Schwartz testified that he did not know of a study involving a TVT-O sling that identified whether the mesh was laser- or mechanically cut, he also testified that one can determine from a study's publication date which type of mesh would have been used. *See* Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 68:12-21. Moreover, Dr. Schwartz noted in his report that the scientific literature shows strong safety and efficacy for mid-urethral slings both before and after laser-cut mesh slings were available. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 28.

Dr. Schwartz's opinions on the characteristics of laser- and mechanically cut mesh are based on both his review of the relevant medical literature and his extensive clinical experience with both types of mesh. His opinions on this topic are based on "good grounds" and meet the standard of reliability under Rule 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993), and should be admitted.

B. Dr. Schwartz's Opinions that the Mesh Does Not Fray, Rope, or Curl in a Clinically Significant Way Are Reliable.

Dr. Schwartz offers the opinion that he has not seen the fraying, roping, or curling suggested by Plaintiffs' experts when he has implanted mechanically cut TVT-O slings, nor is he "aware of published studies indicating the presence of such issues or any clinical significance." Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 28.

Plaintiffs' challenge to this opinion, which is based on Dr. Schwartz's extensive clinical practice and review of the relevant medical literature, should be rejected. Indeed, in *Huskey*, the Court rejected a similar challenge to degradation-related opinions of defendant's expert Dr. Johnson, an obstetrician and gynecologist. 29 F. Supp. 3d at 734-35. The plaintiffs argued that Dr. Johnson was "simply speculating that polypropylene does not degrade or lose particles because he has not seen degradation or particle loss in his practice" and that he "failed to support his opinion with scientific literature." *Id*. The Court disagreed, finding his opinions, which were based "on his review of scientific literature as well as his clinical experience," were reliable. *Id*. at 735. The Court found that, despite that Dr. Johnson's opinion was "not subject to testing" and "not supported by peer-reviewed literature *affirmatively* stating that degradation lacks clinical significance, . . . drawing on clinical experience and a review of relevant literature [wa]s a sufficiently reliable method of forming this particular opinion." *Id*. at 735 (emphasis sic).

Plaintiffs here argue that Dr. Schwartz "fails to employ appropriate methodology in reaching his opinion that mesh does not fray, rope, or curl as he bases the opinion on his clinical practice." Pls.' Mem. (Dkt. 2090) at 5. Plaintiffs contend that Dr. Schwartz did not perform ultrasounds in patients with mesh products in place, only performed gross examinations of explanted mesh and did not "document[] those findings in any way," and did "not perform[] a literature search on fraying, roping, or curling, but had relied on literature provided by Ethicon counsel." *Id*. at 5-6.

As with Dr. Johnson in *Huskey*, Dr. Schwartz's testimony regarding the lack of evidence of fraying, roping, or curling in his clinical experience will be helpful evidence for the jury to evaluate in determining whether those alleged characteristics do occur, whether they can cause Plaintiffs' alleged injuries, and whether they did cause the alleged injuries in a particular case.

He testified that he has performed gross examinations of mesh that he has removed from patients to determine if it is fraying, roping, or curling and has not observed any such issues. Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 65:24-66:6. And he testified that he has read several studies that discussed such issues. *Id.* at 66:18-22. That he did not do a specific literature search on those issues does not render his opinions unscientific or unhelpful. Plaintiffs' counsel established that Dr. Schwartz relied on literature that Ethicon's counsel provided him, but she did not establish that he is relying *only* on literature provided by Ethicon's counsel. *Id*. at 66:23-67:6. Dr. Schwartz's opinions are grounded on his extensive experience implanting and explanting mesh products and are supported by peer-reviewed scientific literature. The Court should find them reliable and admissible under *Daubert* and Rule 702.

C. Dr. Schwartz's Opinions on Mesh Pore Size and Weight Are Adequately Supported and Will Assist the Trier of Fact.

In his report, Dr. Schwartz addresses the choice of a Type I mesh for the TVT devices, citing the Amid study in support of the appropriateness of the pore size of this mesh for this application. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 11, 14. Dr. Schwartz also addresses his disagreement with Plaintiffs' experts' opinion that "larger pore or lighter weight meshes would have been safer to use in the TVT-O sling." *Id*. at 30. In support of his opinions, Dr. Schwartz states that he is "not aware of any studies showing that it would be feasible to use" other meshes proposed by Plaintiffs' experts as a transobturator sling material. *Id*. He addresses the study Plaintiffs' experts have cited in support of their opinions, noting that the procedure studied is very different from the TVT-O procedure, as well as the complications reported in this and other studies cited by Plaintiffs' experts. *Id*. Dr. Schwartz concludes, that in his opinion, "the pore size and weight of the mesh used in the TVT-O is optimal, as evidenced by

the extensive evidence of efficacy and safety" discussed in his report. *Id.*; *see also* Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 11, 14, 29-30 (same for TVT-Secur).

Plaintiffs challenge these opinions on the grounds that Dr. Schwartz has not "researched, published literature, or taught courses on the issue of pore size or mesh density" and that the "sole basis" for Dr. Schwartz's opinion "is reading materials provided to him by Ethicon." Pls.' Mem. (Dkt. 2090) at 6. The Court should reject Plaintiffs' challenge because Dr. Schwartz's testimony is based on both his extensive clinical experience and the peer-reviewed scientific literature. As discussed, the Court has found that "drawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming" opinions regarding issues related to polypropylene characteristics such as degradation. *Huskey*, 29 F. Supp. 3d at 735.

This conclusion applies equally to opinions on pore size and mesh density. Dr. Schwartz's opinions are based on his clinical experience performing over 600 procedures involving a variety of synthetic midurethral slings. *See* Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 1-2; Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 1-2. He cites to numerous studies and scientific articles showing the safety and efficacy of these products, which affirm his conclusion regarding the appropriateness of the mesh pore size and weight. *See* Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 16-24; Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 16, 19-24; *see also supra* Part 0. In addition, Dr. Schwartz directly addresses contrary literature, explaining why he disagrees that the particular study. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 30.

While Dr. Schwartz has not conducted research, published literature, or taught courses on the precise issues of mesh pore size and weight, his evaluation of these issues is scientifically sound and adequately supported by his extensive clinical experience and review of the scientific

literature. His proposed testimony will assist the jury in understanding the evidence and testimony regarding pore size and weight and whether Plaintiffs can meet their burden of proof on the issues of design defect and general and specific causation. The Court should find that Dr. Schwartz's opinions on these topics are reliable and admissible under *Daubert* and Rule 702.

D. Dr. Schwartz's Opinions Regarding Degradation Are Well-Supported and Will Aid the Jury.

Dr. Schwartz disagrees with Plaintiffs' experts that the mesh used in the TVT products degrades. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 29. In Dr. Schwartz's opinion, "If the mesh used in the TVT-O degraded as opined by plaintiffs' experts, surgeons would routinely see that in their practice and the slings would not have the excellent efficacy and safety results that they have." *Id*. Dr. Schwartz bases this opinion on his substantial clinical experience, discussions with colleagues, and review of the extensive medical literature—all of which he believes is inconsistent with the idea that the mesh degrades in any clinically meaningful way. *See id*.; Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 80:13-81:24, 127:11-16. This experience includes over 600 mesh implant procedures, dozens of revision or explant procedures, and gross examination of explanted mesh. Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 1-2; Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 25:23-26:2, 77:2-20. And he couples that experience with reliance on the highest levels of scientific evidence, including meta-analyses and individual studies showing efficacy and safety results that belie Plaintiffs' degradation theory. *See supra* Part 0.

Plaintiffs challenge Dr. Schwartz's degradation opinions on the grounds that he bases them on his clinical experience, he has only performed gross (rather than microscopic) examination of explanted material, and he relies on clinical trials testing the products' efficacy. Pls.' Mem. (Dkt. 2090) at 9. They do not provide any analysis or cite to any authority supporting

these conclusory assertions. *Id*. Plaintiffs note Dr. Schwartz's criticism of the Clave (2010) study, but do not identify any flaw in his analysis. *Id*. They assert that he "did not perform any specific research or seek out any other information regarding degradation," but do not cite any support for this statement. *Id*. They contend that "Dr. Schwartz relies on clinical studies only, failing to review and consider extensive literature that studies the changes that occur in mesh while in vivo," but do not identify any such literature. *Id*. They assert that Dr. Schwartz "has admittedly not applied any scientific methodology in reaching his conclusions," but identify no such admissions. *Id*. at 10.

Plaintiffs' challenge amounts to little more than conclusory, unsupported assertions that Dr. Schwartz's opinions are unreliable. The Court should reject Plaintiffs' arguments and find that Dr. Schwartz's degradation opinions are adequately supported and will assist the jury in assessing the alleged defects and general and specific causation.

E. Dr. Schwartz's Opinions on Mesh Shrinkage and Contracture Are Reliable.

Dr. Schwartz has not seen any clinically significant contraction in the TVT-O or TVT-Secur slings that he has used; in his experience, "tissue ingrowth occurs as expected following implantation of the sling, and while that scar tissue can be expected to contract to an extent, [he has] not seen contraction of the tissue that leads to problems." Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 28; Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 28. Dr. Schwartz bases this opinion in part on his post-procedure examination of patients to assess whether they have any palpable mesh, erosions, or other local issues. Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 69:7-25. He testified that he "can almost never feel the mesh after implantation." *Id*. at 70:1-6. In addition to his clinical experience, he based his opinion on his review of studies that discuss in vivo changes to

mesh, *id*. at 70:14-17, and the "the multitude of high quality literature that attests to the effectiveness of the procedure and, as such, the mesh up to 15-plus years." *Id*. at 72:12-19. He concludes that the lack of clinically relevant mesh contracture is directly related to those results. *Id*. at 72:8-19. Dr. Schwartz's opinions are well-supported by his clinical experience and the scientific literature.

Plaintiffs raise six challenges to these opinions, none of which have merit.

First, Dr. Schwartz's did *not* opine that "tissue and the mesh within do not contract or 'shrink' after implantation." Pls.' Mem. (Dkt. 2090) at 10. Dr. Schwartz testified that he does not believe that it is "the surface area of the mesh that[] [is] reduced;" rather, it is "the ingrowth of fibroblast and other tissues and part of wound healing" that results in the contracture. Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 70:18-24.

Second, Plaintiffs assert that Dr. Schwartz "made no effort during the examinations of his patients to evaluate any differences in the surface area of the mesh" from the date of implant to the date of examination, Pls.' Mem. (Dkt. 2090) at 10, but do not address Dr. Schwartz's response that doing so would be impossible, Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 70:8-11.

Third, Plaintiffs state that Dr. Schwartz "did not perform any vaginal ultrasounds," presumably to evaluate mesh shrinkage or contracture, but do not provide any evidence that such a test would be any more reliable than the digital examination Dr. Schwartz has performed in his patients to look for this very problem. Pls.' Mem. (Dkt. 2090) at 10.

Fourth, Plaintiffs inaccurately state that "Dr. Schwartz was unable to name any articles that disagreed with his position." *Id*. Dr. Schwartz was asked if he "evaluate[d] any studies that focus[ed] on the clinical significance of mesh contracture in patients who have been implanted

with a midurethral sling"; he responded that he "recall[ed] a study that looked at explanted mesh" but could not remember the details, other than that he "did[] [not] find the conclusion very clinically useful." Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 73:10-74:15. He made clear he would have to go through his materials to identify particular studies that supported his opinions, but counsel did not give him an opportunity to do so. *Id*. at 72:8-73:5.

Fifth, Plaintiffs argue that Dr. Schwartz has not performed any studies to measure contracture of mesh. Pls.' Mem. (Dkt. 2090) at 10. But, as the Court has made clear, "drawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming" opinions such as these. *Huskey*, 29 F. Supp. 3d at 735.

And *sixth*, Plaintiffs contend that Dr. Schwartz's opinions should be excluded "because of his complete failure to consider or account for any contrary scientific authority." Pls.' Mem. (Dkt. 2090) at 10-11. According to Plaintiffs, "numerous published, peer-reviewed articles[] . . . establish *beyond reasonable scientific dispute* the general acceptance of the phenomenon of *in vivo* mesh shrinkage." *Id*. at 11 (emphasis added). Yet the nine articles Plaintiffs cite in support of this aggressive position do not constitute "[t]he overwhelming weight of the published scientific literature" on the subject of contracture of the mesh used in the products at issue here. *Id*. at 12-13. On the contrary, not a single one of these articles studies mesh contracture and shrinkage of mid-urethral slings.[1] All involve much larger sheets of mesh, different meshes,

[1] Feiner (2010) is a mere case series and involves pelvic organ prolapse products. Ex. F to Pls.' Mot. (Dkt. 2089-6). Garcia-Urena (2007) is an animal study of mesh products used in hernia repair. Ex. G to Pls.' Mot. (Dkt. 2089-7). Hansen (2013) involved the visualization of mesh implants for hernia repair. Ex. H to Pls.' Mot. (Dkt. 2089-8). Klinge (1998) is a study of 8 x 10 cm meshes implanted in dogs. Ex. I to Pls.' Mot. (Dkt. 2089-9). Klinge (1999) is a review of "only a few samples of mesh"—with no discussion of how the samples were selected—from revisions of mesh used in incisional hernia repairs. *See generally* Ex. J to Pls.' Mot. (Dkt. 2089-10); *id*. at 670. Klosterhalfen (2005) involves mesh products used for hernia repair. Ex. K to Pls.' Mot. (Dkt. 2089-11). Letouzey (2009) is an abstract of a study of the use of 6 x 12 cm mesh for

mesh products placed in different parts of the body, and/or mesh products placed in animals. In support of his opinions, Dr. Schwartz relied on systematic reviews and meta-analyses, randomized controlled trials, long-term studies, and registry studies of mid-urethral slings—in other words, exceptionally high-quality scientific information specific to the products on which he is offering opinions. *See supra* Part II. As Dr. Schwartz explained, that substantial body of evidence is consistent with his clinical experience and at odds with the idea that the mesh in mid-urethral slings contracts in a clinically significant way. Dr. Schwartz's opinions are not unreliable because he "fail[ed] to consider or account for" literature involving different products used to treat different conditions. Pls.' Mem. (Dkt. 2090) at 13. Dr. Schwartz's opinions are reliable and should be admitted.

III. Dr. Schwartz's Testimony on the TVT's Instructions for Use Is Reliable.

Dr. Schwartz proposes to testify that any failure by Ethicon to include in the TVT IFU warnings about risks surgeons are independently aware of does not render the warnings inadequate. *See* Ex. B to Pls.' Mot. (Dkt. 2089-2), Schwartz TVT-O Report at 32. As Dr. Schwartz notes, the risks of "infection, inflammation, bleeding, scarring, bladder damage, bowel damage, nerve damage, ureteral damage, pain, pelvic pain, dyspareunia, groin pain, bladder or bowel dysfunction, fistula, anesthetic risks, wound complications such as erosion, wound dehiscence, exposure, wound herniation, hematoma, need for reoperation, failure of the operation, and anesthetic risks" are *inherent in any pelvic floor surgery*. *Id.*; *see also id.* at 6 ("All continence surgeries have similar risks including: bleeding, infection, persistent or recurrent SUI, voiding dysfunction including overactive bladder symptoms and urinary retention,

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cystocele repair. Ex. L to Pls.' Mot. (Dkt. 2089-12). Svabik (2009) reports a poster presentation of a study of Prolift and self-cut mesh used in vaginal reconstructive surgery. Ex. M to Pls.' Mot. (Dkt. 2089-13). Tunn (2007) is a study of products used for pelvic organ prolapse. Ex. N to Pls.' Mot. (Dkt. 2089-14).

chronic pain, dyspareunia, injury to the vagina/urethra/bladder/ureters/pelvic blood vessels/pelvic nerves/bowel/pubic bone, and wound healing complications."). Similarly, Dr. Schwartz would testify that there is no need to warn surgeons "about the severity, frequency, or permanency of any of these complications" because "[s]urgeons know from their education, training, and experience that complications can be mild, moderate, or severe, permanent or temporary, and data on complication frequency is available in peer-reviewed literature, which surgeons have an obligation to review." *Id*. at 32.

Dr. Schwartz proposes to testify that these are the types of risks that surgeons who perform continence surgeries are aware of as a result of their medical training. This opinion is supported by Dr. Schwartz's own training and his training of other surgeons. *Id*. at 1-3. This information will be helpful to the jury because a manufacturer is not liable for a failure to warn of risks of which the physician was already independently aware. *See, e.g.*, *Talley v. Danek Med., Inc*., 7 F. Supp. 2d 725, 730 (E.D. Va. 1998) (citing *Stanback v. Parke, Davis & Co*., 657 F.2d 642, 645 (4th Cir. 1981)), *aff'd*, 179 F.3d 154 (4th Cir. 1999). In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added). Here, the device IFUs restrict their use to surgeons familiar with traditional surgical techniques used to treat stress urinary incontinence. *E.g.*, Ex. 1, TVT IFU, ETH.MESH.24033584 ("Users should be familiar with surgical technique[s] for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System."); Ex. 2, TVT-O IFU, HMESH_ETH_11043472 (stating device should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device").

Plaintiffs argue that Dr. Schwartz's opinions should be excluded because he is not familiar with the standards applicable to medical device IFUs or the process by which IFUs are developed and approved. Pls.' Mem. (Dkt. 2090) at 14. Plaintiffs do not support these assertions with citations to any of Dr. Schwartz's testimony or to his reports. *Id*. Nor do Plaintiffs address Dr. Schwartz's testimony to the contrary. *E.g.*, Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 135:10-136:16 (testifying that he considered the FDA's 1991 Device Labeling Guidance in forming his opinions about warning adequacy).

Contrary to Plaintiffs' argument, Dr. Schwartz does not rely "solely on his own personal opinion and experience." Pls.' Mem. (Dkt. 2090) at 14. He relies on his training in surgical procedures and their inherent risks, his training of other surgeons on those topics, and his review not only of the IFUs of the TVT products, but on FDA labeling guidance as well. Dr. Schwartz's opinions are well-supported and should be deemed reliable.

IV. Dr. Schwartz's Testimony Regarding Ethicon's Professional Education Program Is Reliable.

Dr. Schwartz testified that "Ethicon provided [him] with adequate training and [he] in turn provided other surgeons with adequate training." Ex. E to Pls.' Mot. (Dkt. 2089-5), Schwartz 3/25/16 TVT-O Dep. Tr. 92:6-11.[2] He acknowledged he cannot testify to all surgeons' experience with the training, but that does not render his opinions about his own experience with the Ethicon training program unscientific or unhelpful for the jury. Dr. Schwartz's opinions on

[2] Contrary to Plaintiffs' argument, Dr. Schwartz did not testify "that he did not hold an opinion regarding the effectiveness of the program in relation to the products but only that he had had a positive experience." Pls.' Mem. (Dkt. 2090) at 16. The exchange cited by Plaintiffs was as follows: "Q. . . . Do you hold an opinion about Ethicon's professional education program in relation to the TVT-Secur? A. My experience has all been positive and very helpful. Q. But you are not opining as to their overall training program? Do I understand that correctly? [objection] The Witness: I'm just commenting upon what their—how their training program interacted with me." Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz TVT-Secur Dep. Tr. 58:24-59:9.

this topic are adequately supported by his experience and will help the trier of fact assess the adequacy of the warnings that Ethicon provided to surgeons. Plaintiffs' arguments to the contrary should be rejected. Dr. Schwartz's opinions on this topic are reliable and admissible.

V. Dr. Schwartz's Opinions regarding the TVT-Secur Are Reliable.

Dr. Schwartz's opinions that the TVT-Secur is safe and effective are supported by his clinical experience and numerous scientific studies. Dr. Schwartz performed several hundred TVT-Secur procedures, Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 2, and found it to have many advantages over other surgical treatments for stress urinary incontinence:

> I found the TVT-Secur to be less invasive than other surgical SUI treatments, to involve less tissue dissection, to cause less bleeding, and to result in no need for post-operative catheterization. The fact that the device could be implanted via a single incision meant that there were no non-vaginal wounds that had to heal or had the possibility of getting infected. The TVT-Secur was essentially pain-free for my patients, especially compared to other available treatments. I did not prescribe pain medication for my TVT-Secur patients unless they requested it, and they rarely did so. The patients were back to normal, non-strenuous activities within 2-3 days after the procedure. After a week, they were back to work. . . . The TVT-Secur was an excellent device to have in the surgeon's toolkit, especially for women in jobs such as teachers, waitresses, nurses, or other physically demanding jobs where they needed to get back as soon as possible to work. Overall, my TVT-Secur patients did great. If the TVT-Secur was still available, I would still be using it.

Id. at 18.

In addition to his clinical experience, Dr. Schwartz considered many of the numerous studies of the TVT-Secur. *Id*. at 19 (noting that at least 83 TVT-Secur studies were undertaken between 2006 and 2014, 19 of which were randomized controlled trials). In reaching his opinions, he relied on high-level evidence directly applicable to this product, including systematic reviews and meta-analyses regarding single-incision slings. *See, e.g.*, *id*. at n.13 (discussing Walsh (2011) systematic review); *id*. at n.17 (discussing Schimpf (2014) review).

Plaintiffs argue that Dr. Schwartz's opinions on the safety and efficacy of TVT-Secur should be excluded because he "'selectively'" relied on studies that support his opinion, while "[t]he overwhelming weight of the published scientific literature establishes that the TVT-Secur is not effective and in some instances, not safe." Pls.' Mem. (Dkt. 2090) at 18. Untrue.

Plaintiffs questioned Dr. Schwartz on a systematic review of data on single-incision slings, including the TVT-Secur. Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 38:6-12 (discussing Nambiar (2014)). The Nambiar (2014) authors concluded that the efficacy of the TVT-Secur and the risk of exposures, erosion, and operative blood loss were inferior in comparison to standard mid-urethral slings. *Id*. at 40:18-23. While Dr. Schwartz did not cite this review in his report, he had read it and he had also considered other systematic reviews and meta-analyses of the TVT-Secur in forming his opinions. Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 14-17; Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 71:11-19. Dr. Schwartz noted that systematic reviews and meta-analyses of literature sometimes analyze different sets of literature, even though they may set out to look at all of the literature about a certain device. *Id*. at 77:14-78:5.

Contrary to Plaintiffs' contention that Dr. Schwartz "ignored" studies that did not support his opinions, Pls.' Mem. (Dkt. 2090) at 18, Dr. Schwartz considered many studies, including systematic reviews and meta-analyses, that were critical of single-incision slings in general and the TVT-Secur in particular, *see, e.g.*, Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at 20 (discussing Walsh (2011)); Ex. 3, Colin A. Walsh, *TVT-Secur Mini-sling for Stress Urinary Incontinence: A Review of Outcomes at 12 Months*, 108 BJU INT'L 652, 652 (2011) ("Longer-term studies and randomized comparisons with more established [mid-urethral slings] are required before TVT-S should be routinely used in the surgical treatment of stress urinary

incontinence."); Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 81:13-82:11 (discussing Walsh (2011)). He ultimately concluded, "[W]hile there is some data that is poor, there are other high quality studies that show very favorable data, and my experience has mirrored the more favorable ones." *Id*. at 60:20-23; *id*. at 71:15-72:17 (noting that some randomized controlled trials he considered reported very strong efficacy rates for the TVT-Secur—consistent with his experience—while others report lower efficacy rates).

Plaintiffs also claim that Dr. Schwartz "failed to consider" four studies that, according to Plaintiffs, "conclude that the TVT is not effective (and in some instances not safe)." Pls.' Mem. (Dkt. 2090) at 17-18 (citing Hota (2012), Cornu (2010), Barber (2012), and Masata (2012)). Again, Plaintiffs' contentions are incorrect:

- Barber (2012), Ex. S to Pls.' Mot. (Dkt. 2089-19), is cited in Dr. Schwartz's TVT-Secur report. Ex. C to Pls.' Mot. (Dkt. 2089-3), Schwartz TVT-Secur Report at n.15.

- Hota (2012), Ex. Q to Pls.' Mot. (Dkt. 2089-17), was among the articles Dr. Schwartz brought to his deposition, some of which had been provided by Ethicon counsel, some of which had not. Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 6:17-7:8, 9:21-10:2. Dr. Schwartz considered this article before his deposition and concluded that the study, which reported a 19.1 percent rate of mesh exposure at one year was "an outlier," which he attributed in part "to the slightly more technically challenging nature of performing the procedure." *Id*. at 26:21-27:21, 28:12-17. Furthermore, the authors also reported overall improvement in quality of life at both twelve weeks and one year in TVT-Secur patients, with no difference between that group and the TVT-O group. *Id*. at 62:18-63:11. The authors also reported overall improvement in subjective cure rates after both procedures, as well as a lower incidence of postoperative pain in the TVT-Secur group. *Id*. at 63:13-64:20.

- Cornu (2010), Ex. R to Pls.' Mot. (Dkt. 2089-18), was among the articles that Dr. Schwartz obtained through his online research before his deposition. Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 10:22-11:17. Cornu is not a controlled trial, it is a study of 45 consecutive patients treated at a single institution by a single surgeon, who reported a failure rate of 42 percent at three-year follow-up. Ex. R to Pls.' Mot. (Dkt. 2089-18) at 1-2. Dr. Schwartz characterized it as "the most significant outlier of all of the TVT-Secur studies [he] could find." Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 48:10-49:12.

- Masata (2012), Pls.' Ex. T (Dkt. 2089-20), was not a study with which Dr. Schwartz was familiar. Ex. O to Pls.' Mot. (Dkt. 2089-15), Schwartz 3/25/16 TVT-Secur Dep. Tr. 29:22-30:8. In addition to the results focused on by Plaintiffs' counsel, however, the study also showed that there was a significant improvement in quality of life in all of the study groups, including the TVT-Secur group, with no significant difference in the overall satisfaction in the groups. *Id*. at 64:22-65:10. It also showed no statistically significant difference between the groups in terms of tape erosion or re-operation for SUI. *Id*. at 66:2-20.

These studies do not negate the myriad of high-level evidence relied on by Dr. Schwartz, nor do they establish that Dr. Schwartz's review of the relevant literature was insufficient, rendering his opinions inadmissible. Dr. Schwartz based his opinions on both his clinical experience treating hundreds of patients with the TVT-Secur, a wide-ranging review of the dozens of studies of the product, and reliance on numerous high-quality systematic reviews and meta-analyses and randomized clinical trials that support his opinions. His opinions are well-founded and reliable and should be admitted.

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Brian N. Schwartz, M.D.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ *Rita A. Maimbourg*

Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Telephone: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Telephone: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com